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EXAMINER	
CARTER, KENDRA D	
ART UNIT	**PAPER NUMBER**
1617	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/505,299	WAUGH ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-68,70-76 and 78-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-68,70-76 and 78-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/07;1/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of December 17, 2007 made to the office action filed June 19, 2007. Claims 44-68, 70-76 and 78-85 are pending. Claims 44-68, 70-76 and 78-85 are amended and claims 69 and 77 are cancelled.

In light of the amendments, the following rejections are withdrawn: 1) the 35 U.S.C. 103(a) rejection of claims 68, 69, 71, 76-77, 79, 84 and 85 as being unpatentable over Rothbard et al.; 2) the 35 U.S.C. 103(a) rejection of claims 70 and 78 as being unpatentable over Rothbard et al. as applied to claims 68, 69, 71, 76-77, 79, 84 and 85 above, in view of Kull, Jr. et al.; 3) the 35 U.S.C. 103(a) rejection of claims 72 and 80 as being unpatentable over Rothbard et al. as applied to claims 68, 69, 71, 76-77, 79, 84 and 85 above, in view of Porter et al.; the 35 U.S.C. 103(a) rejection of claims 73 and 81 as being unpatentable over Rothbard et al. as applied to claims 68, 69, 71, 76-77, 79, 84 and 85 above, in view of Kent et al.; 4) the 35 U.S.C. 103(a) rejection of claims 74 and 82 as being unpatentable over Rothbard et al. as applied to claims 68, 69, 71, 76-77, 79, 84 and 85 above, in view of Ribier et al.; and 5) the 35 U.S.C. 103(a) rejection of claims 75 and 83 as being unpatentable over Rothbard et al. as applied to claims 68, 69, 71, 76-77, 79, 84 and 85 above, in view of Clark, Jr. et al.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 44-67 as being unpatentable over Rothbard et al. were found not persuasive, thus the rejection is upheld.

The Examiner would like to note that claim 76 was not in the proper amended format because the previous claim language was not present and struck out with a line. For compact prosecution, the Examiner has examined the amended claim.

Due to the amendment to the claims, the modified and new 103(a) and 112, first paragraph rejections are made below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(1) Claims 70 and 78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hair loss, does not reasonably provide enablement for preventing hair loss. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of preventing hair loss. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 70 is drawn to a "method according to claim 68, wherein the cosmetic effect is selected from the group consisting of prevention of hair loss, promotion of hair regrowth, increase in length or thickness of eyebrows."

(2) The breadth of the claims:

Claims 70 and 78 embraces and reads on completely preventing hair loss. The specification does not enable the prevention of hair loss.

(3) The state of the prior art:

The state of the art regarding completely preventing hair loss is very low or do not exist. Sinclair teaches that there are only treatments available for various forms of hair loss, but none are curative, and that patients need to understand the limitations or such treatments and the components of management (see page 868, column 2, conclusion in its entirety).

(4) The predictability or unpredictability of the art:

The predictability of completely preventing hair loss is relatively low. Therefore, to one skilled in the art, prevention of hair loss is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the prevention of hair is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that completely prevents hair loss. The specification teaches an example for topical enhancement of hair growth, but not the prevention of hair loss (see page 10, example 1). Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on the complete prevention of hair loss. As discussed above the specification fails to provide any support for completely preventing hair loss. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for treating hair loss, but not for preventing it.

(2) Claims 74 and 82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating wrinkles, does not reasonably provide enablement for the stabilization or remodeling of fat. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of stabilizing or remodeling fat. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400

(CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 74 is drawn to a "method according to claim 68, wherein said cosmetic effect is the stabilization or remodeling of fat."

(2) The breadth of the claims:

Claims 74 and 82 embraces and reads on all conditions that would benefit from the stabilization or remodeling of fat such as weight management or wrinkles. The specification does not enable the treatment of all conditions that would benefit from the stabilization or remodeling of fat.

(3) The state of the prior art:

The state of the art regarding treating all conditions that would benefit from the stabilization or remodeling of fat is very low or do not exist.

(4) The predictability or unpredictability of the art:

The predictability of knowing and then treating all conditions that would benefit from the stabilization or remodeling of fat is low. Therefore, to one skilled in the art, treating all conditions that would benefit from the stabilization or remodeling of fat is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to treating all conditions that would benefit from the stabilization or remodeling of fat is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that treating all conditions that would benefit from the stabilization or remodeling of fat. The specification teaches that vasodilation may lead to a lesser appearance of certain fine lines and wrinkles (see page 1, last paragraph, last 2 lines). The current specification reaches to all the conditions that exist and those that still have not been determined that relate to the treatment of stabilizing or remodeling fat, with no enablement or prior art for all of these conditions. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on the treatment of all conditions that would benefit from the stabilization or remodeling of fat. As discussed above the specification fails to provide any support for treating all conditions that would benefit from the stabilization or remodeling of fat. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for treating wrinkles, but not for treating the stabilization or remodeling of fat.

(3) Claims 71, 79, 84 and 85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alleviating textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, does not reasonably provide enablement for alleviating all signs of aging, particularly discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of alleviating signs of aging in skin such as textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, does not reasonably provide enablement for alleviating discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 71 is drawn to a “method according to claim 68, wherein the cosmetic effect is the alleviation of signs of aging in skin.” The claim 84 is drawn to a “method

according to claim 71, wherein said signs of skin aging are selected from the group consisting of textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system."

(2) The breadth of the claims:

Claims 71, 79, 84 and 85 embraces and reads on alleviating all to a large genus of different signs of aging. The specification does not enable alleviation of all signs of aging, or specifically discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system.

(3) The state of the prior art:

The state of the art regarding treating all signs of aging or all forms of skin discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system is very low or do not exist. Gazzani teaches a composition to treat wrinkles (see abstract). The wrinkles are a result of the blood circulation within the germinative layer

being hindered and the feeding of nutrient substances being reduced, which creates an appearance of looking old-looking (see column 1, lines 27-31). Gazzani does not teach that the increase of blood (i.e. such as through vasodilation) to this area would treat all of the signs of aging.

(4) The predictability or unpredictability of the art:

The predictability of alleviating all signs of aging, or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system is relatively low. Therefore, to one skilled in the art, alleviation of all or all forms of the above conditions is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to alleviating all signs of aging, or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system is completely lacking. The specification as filed does not speak on or

show any working examples any studies performed that alleviate all signs of aging or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on alleviating all signs of aging, or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system. As discussed above the specification fails to provide any support for alleviating all the signs of aging or all the forms discussed above in light of prior art teaching that the increase in blood treats wrinkles (i.e. textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil) but not all signs of aging nor those discussed above. One skilled in the art would need to apply the composition to each form of aging to see if it was effective to treat the condition (i.e. epidermis, dermis, blotching). Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its

successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for alleviating textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, but not for alleviating all signs of aging, particularly discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system.

(4) Claims 75 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of treating gum regression. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 75 is drawn to a "method according to claim 68, wherein the cosmetic effect is the treatment of gum regression."

(2) The breadth of the claims:

Claims 75 and 83 embraces and reads on treating gum regression. The specification does not enable the treatment of gum regression.

(3) The state of the prior art:

The state of the art regarding treating gum regression is medium or high. Chan (US 5,922,756) teaches that excess nitric oxide (i.e. a vasodilator) contributes to chronic inflammation (see column 1, lines 40-43), in which Chan teaches a treatment of chronic and acute inflammatory conditions such as periodontitis by inhibiting nitric oxide synthase (see column 2, lines 20-25 and column 3, line 65). It is known in the art that inflammation leads to gum recession and conditions generically known as periodontal diseases (see Bowen et al.; US 3,952,092; column 1, lines 25-28). Thus, inflammation causes gum recession and gum inflammation is contributed to the excess production of

nitric oxide. Therefore, one skilled in the art would not want to provide a vasodilator to treat gum recession.

(4) The predictability or unpredictability of the art:

The predictability of treating gum regression is relatively medium to high. Therefore, to one skilled in the art, treating gum regression is somewhat predictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the treating gum regression is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that treats gum regression with the claimed compound by means of dilating blood vessels (i.e. vasodilation) of the gum. The specification teaches that the compositions of the invention "may" reduce the appearance of gum regression (see page 6, paragraph 2, last 2 lines), but no examples showing that the compositions actually treat gum regression in light of prior art teaching that vasodilators cause gum regression. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on treating gum regression. As discussed above the specification fails to provide any support for treating gum regression. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is not enabled for treating gum regression.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 44-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothbard et al (U.S. Patent Application Publication No. 2002/0009491).

Rothbard et al. teaches providing compositions for enhancing the delivery of drugs and other agents across a biological barrier, such as skin, the composition

employing a delivery enhancing transporter, such as a poly-arginine molecule that is between 6 and 50 residues in length (see abstract, in particular.) Rothbard teaches that examples of such delivery enhancing transporters can comprise from 7 to 15 amidino moieties, such as heptamers, octamers, nonamers and the like of arginine (see paragraph 0048, in particular.) Rothbard et al. furthermore teaches that the amino acids can be L amino acids (see paragraph 0055, in particular.) Rothbard et al. teaches that the compositions comprising the polyarginine molecule can comprise a conventional pharmaceutical carrier and can be formulated for topical administration in a suitable format, such as a lotion (see paragraphs 0128 and 0134, in particular), and thus teaches providing a dermatologically acceptable vehicle.

Rothbard et al. does not teach a specific example of composition having a polymer comprising from 7 to 15 subunits of L-arginine in a cosmetically or dermatologically acceptable vehicle. However, as Rothbard et al. teaches that the transport enhancing polymers can comprise from 7 to 15 amidino moieties, such as heptamers, octamers and nonamers of arginine, which may be L-arginines, and furthermore teaches that such transport enhancing agent can be formulated with pharmaceutical carriers for topical administration, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide a polymer having a number of arginine subunits within the range recited in claim 44, and with a dermatologically acceptable vehicle, with the expectation of providing a transport

enhancing composition suitable for topical application.

Regarding the recitation that the composition comprises a "vasodilating amount of polymer," as recited in claims 44 and 56, it is noted that Rothbard et al. teaches the composition having the transport enhancer can generally comprise from about 5% to about 75% by weight of a compound/transport combination (see paragraph 0128.) An amount of 5% to 75% is believed be substantial enough range to provide overlap and/or to come close to an amount that would also have vasodilating properties. Furthermore, • it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the transport enhancer provided in the composition, according to the guidance provided by Rothbard et al, to provide a composition having desired transport properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955.)

Regarding claims 44 and 56, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising," absent a clear indication in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase "consisting essentially of." See, e.g., PPG, 156 F.3d at

1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding independent claim 56, Rothbard et al. furthermore teaches that peptides comprising arginine in addition to other amino acid residues can also be used as the delivery-enhancing polymer, and furthermore teaches that the delivery-enhancing transporters of the invention can be flanked by, or interrupted by, one or even more than one non-guanidino/non-amidino subunits (such as glycine, alanine and cysteine), that do not significantly affect the rate of transmembrane transport of the delivery-enhancing compound compositions (see paragraphs 0048 and 0071, in particular.) Accordingly, Rothbard et al. teaches the polymer having contiguous arginine subunits, with a number of subunits that overlaps with the range claimed in claim 56, the polymer being flanked by one amino acid other than L-arginine, in which the L-arginine subunits would be situated at the C-terminus or the N-terminus of the polymer, as recited in claim 56. Rothbard et al. furthermore teaches providing a dermatologically acceptable carrier in combination with delivery-enhancing polymers, as discussed for claim 44 above, and thus the composition recited in claim 56 is also obvious over the teachings of Rothbard et al.

Regarding claims 45-47 and 57-59, Rothbard et al. teaches providing heptamers of arginine (see paragraph 0048, in particular), which is a polymer containing 7 contiguous arginine subunits, and thus meets the limitation of these claims. Regarding

claims 48-50 and 60-62, Rothbard et al. teaches that the delivery-enhancing polymer can be formulated as a lotion for application to skin (see paragraph 0134, in particular.)

Regarding claims 51 and 63, Rothbard et al. teaches the subunits are L-arginine (see paragraph 0048, in particular.)

Regarding claims 52-53 and 64-66, and the claim limitation that the composition is cosmetic, Rothbard et al. teaches the topical composition can further comprise skin care actives such as vitamins, antibacterial and analgesics, as well as sunscreen components, among others (see paragraphs 0140- 0152, in particular.)

Regarding claims 55 and 67, Rothbard et al. furthermore teaches that small organic molecule agents can be combined with the transporters to facilitate or enhance transport (see paragraph 0076, in particular.) Rothbard et al. teaches that such compounds can include small organic molecules that have poor solubilities in aqueous liquids (see paragraph 0076, in particular), and thus are hydrophobic. Rothbard et al. furthermore teaches that the biologically active agent and delivery enhancing transporter are linked by an ionic association, such as between the charged arginine side chain and a charged group on the biologically active agent (see paragraph 0044 and Figure 1, in particular.) While Rothbard et al. does not specifically exemplify linking the biologically active agent to the side chain of the terminal L-arginine subunit, it is considered that one or ordinary skill in the art at the time the invention was made would

have found it obvious to provide such an association, based on the ion pair teachings of Rothbard et al, with the expectation of providing a suitable transport pair for skin treatment.

(2) Claims 68, 70, 72, 73, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooke et al. (US 6,605,115 B1) in view of Applicant's admitted prior art (see specification page 1, paragraph 2, lines 1 and 8-11; and the last paragraph to page 2, first paragraph), in further view of Fossel (US 5,895,658).

Cooke et al. teaches a method of increasing nitric oxide (NO) production in a vascular cell or tissue by contacting a polymer consisting of from 6 to about 30 amino acid subunits such as 7 to 15 L-arginine residues (i.e. Applicant's compound; see column 4, lines 12-18 and claim 26). The arginine oligomers were found to be significantly more efficacious than equivalent amounts of free arginine monomers, which is not significantly taken up by the walls of the arterial and venous segments (see column 10, lines 17-20). The (L)-arginine oligomers enhance NO production by supplementing intracellular (L)-arginine levels (see column 10, lines 26-38).

Cooke et al. does not teach a cosmetic effect, specifically skin sensitivity, lip plumpness, lip color, lip contour, promotion of hair regrowth, increase in length or thickness of eyelashes, and increase in length or thickness of eyebrows (claims 68, 70,

72, 73, 76, 78, 80 and 81). Cooke et al. also does not specifically teach that the blood vessels are dilated (claims 68 and 76) or topical application (claim 76).

The Applicant admits in the prior art that NO is formed from L-arginine, and that NO is a vasodilator (see page 1, paragraph 2, lines 1 and 8-11). Additionally, the Applicant teaches that (see page 1, last paragraph) that highly vasularized tissues such as lips, gums, genitalia, etc, vasodilation leads to transient, reversible increases in tissue mass and sensitivity. A method for enhancing vasodilation in these tissues would therefore lead to a tissue with enlarged appearance such as lip size (i.e. cosmetic effects; lip plumpness/contour; addresses claims 68, 72, 76 and 80), create a natural blush, or enhanced sensitivity of the skin (addresses claims 73 and 81).

Fossel teaches that a topical (see column 1, lines 1-3) composition comprising L-arginine as the main substance to relax the blood vessels and thus permitting enhancement of blood flow to the tissue (see abstract, lines 1-8), to achieve growth of hair (see column 1, line 10; addresses claims 70 and 78).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Cooke et al. and a method to specifically dilate blood vessels in a region of the body to achieve a cosmetic effect such as those disclosed in claims 68, 70, 72, 73, 76, 78, 80 and 81 because of the following teaching: (1) Cooke et al. teach that the applicant's compound increases the

production of nitric oxide; (2) the Applicant teaches that nitric oxide is a vasodilator; (3) Cooke et al. teach that the (L)-arginine oligomers enhance NO production by supplementing intracellular (L)-arginine levels (see column 10, lines 26-38); (4) Fossel teaches that a topical composition of L-arginine increases the blood flow to a tissue to achieve growth of hair (see column 1, lines 1-5); and (5) the Applicant teaches that highly vascularized tissues such as lips, gums, genitalia, etc. lead to increase in tissue mass, which would obviously result in cosmetic effects like lip plumpness and skin sensitivity.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Cooke et al. and topical application of the composition because of the following teaching: (1) Cooke et al. teaches that the arginine oligomers were found to be significantly more efficacious than equivalent amounts of free arginine monomers, which is not significantly taken up by the walls of the arterial and venous segments (see column 10, lines 17-20); and (2) Fossel teaches that a topical composition of L-arginine increases the blood flow to a tissue to achieve growth of hair (see column 1, lines 1-5).

(3) Claims 71, 74, 79, 82, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooke et al. (US 6,605,115 B1) in view of Applicant's admitted prior art (see specification (see page 1, paragraph 2, lines 1 and 8-11; and the last

paragraph to page 2, first paragraph) and Fossel (US 5,895,658) as applied to claims 68, 70, 72, 73, 76, 78, 80 and 81 above, in further view of Gazzani (US 5,053,230).

The teachings of Cooke et al., Applicant's admitted prior art, and Fossel are as applied to claims 68, 70, 72, 73, 76, 78, 80 and 81 above.

Cooke et al. and Fossel do not teach wherein the cosmetic effect is that disclosed in claims 71, 74, 79, 82, 84 or 85.

Gazzani teaches that when blood circulation towards and within the germinative layer is hindered, or the feeding of nutrient substances is reduced (which is known that feeding takes place by blood circulation), the layer becomes more and more atrophied and the skin becomes wrinkled and old-looking, while hair follicles lack the capacity for forming new hair (see column 1, lines 25-40).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Cooke et al. and wherein the cosmetic effect is that disclosed in claims 71, 74, 79, 82, 84 or 85 because of the following teaching: (1) Cooke et al. teach that the applicant's compound increases the production of nitric oxide; (2) the Applicant admits that the prior art teaches that nitric oxide is a vasodilator; (3) Fossel teaches that a topical composition of L-arginine increases the

blood flow to a tissue to achieve growth of hair (see column 1, lines 1-5); and (4) Gazzani teaches that when blood circulation towards and within the germinative layer is hindered, or the feeding of nutrient substances is reduced (which is known that feeding takes place by blood circulation), the layer becomes more and more atrophied and the skin becomes wrinkled and old-looking, while hair follicles lack the capacity for forming new hair (see column 1, lines 25-40). Thus, upon increasing the blood circulation with an L-arginine oligomer to the skin or hair follicles, the tissue area will regain nutrients and blood to reduce wrinkles and the look of old age (i.e signs of aging, loss of skin firmness, loss of skin tightness, loss of skin recoil).

Response to Arguments

Applicant's arguments filed December 19, 2007 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 68, 70-76 and 78-85 have been considered but are moot in view of the new ground(s) of rejection.

> The Applicant argues that Rothbard does not teach or suggest a "cosmetic" formulation. Also, the Applicants have recognized that arginine oligomers, without the presence of an additional biologically active agent, can have a beneficial effect, such as a cosmetic effect.

The Examiner disagrees because Rothbard teaches that the composition is topical and can further comprise skin care actives such as vitamins, antibacterial and analgesics, as well as sunscreen components, among others (see paragraphs 0140-0152, in particular.) This obviously teaches that the compositions can be used in cosmetic formulations. In regards to the intended use of the composition to give a cosmetic effect, the claims are only given weight to a composition and not a method. Thus, the intended use of the composition claims do not receive weight.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617